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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/726,880	11/30/2000	Chyi-Cheng Chen	20223 US (C38435/120240)	1470
7590 03/08/2007 STEPHEN J. BROWN,ESQ. BRYAN CAVE LLP 1290 AVE. OF THE AMERICAS 33rd floor NEW YORK,, NY 10104			EXAMINER CHANNAVAJJALA, LAKSHMI SARADA	
			ART UNIT 1615	PAPER NUMBER

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/08/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

09/726,880

Applicant(s)

CHEN ET AL.

Examiner

Lakshmi S. Channavajjala

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 December 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-15 and 17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-15 and 17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>12-22-06</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Receipt of response dated 12-11-06 is acknowledged.

Claims 1, 3-15 and 17 are pending in the instant application.

Response to Arguments

Applicant's arguments, see pages 2-16 of response filed 12-11-06 as well as the declarations filed by Mr. Stein (3-28-05) and Dr. Chen (3-28-05), with respect to the rejection(s) of claim(s) Claims 1 and 7-15 were rejected under 35 USC § 103(a) as being unpatentable over Tritsch and rejection of claims 1, 3-15, and 17 were rejected under 35 USC §103(a) as being unpatentable over Stein in view of Tritsch or Tritsch in view of Stein have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made as follows:

35 U.S.C. 103 Rejections

1. Claims 1, 7-15 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/42134 (WO).

Instant claim 1 is directed to a powder composition comprising at least one fat-soluble vitamin in a matrix consisting of an emulsion-forming composition, wherein the fat-soluble vitamin is present in the powder composition in the form of solid droplets having an average diameter of about 80 to 120 nanometers. The claimed matrix is selected from the group consisting of proteins and polysaccharide gums.

WO teaches a spray dried tabletable powders comprising high edible oil loadings based on non-hydrolyzed gelatin and a method of making such spray dried tabletable powders, with a droplet size of less than 0.8 microns (page 5-6), preferably 0.05 to 0.8 microns (page 6, L 6-8). WO teaches edible oils include vitamins such as vitamin A, Vitamin E etc (page 6, L 23-42). Further, WO teaches 40%-90% edible oil and 10-60% gelatin in the composition, which percentages overlap with the claimed percentages of vitamin and matrix (claim 14). While WO teaches the same fat-soluble vitamins, same protein and the droplet size of the fat-soluble materials in the range of 0.05 to 0.8 microns (50 to 800 nm), WO does not teach the exact range of the claimed powders. However, WO teaches that the vitamin powders can have a size as low as 50 nm and as high as 800 nm. Accordingly, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to optimize the size of the droplets or vitamin powders and still achieve the same high loading of oil soluble vitamins so as to prepare a tabletable preparation. Further, optimizing the amounts and ratios of vitamin and gelatin to arrive at the claimed ratios would have been within the scope of a skilled artisan.

2. Claims 1, 7, 9, 11-15 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/42134 (WO) in view of EP 937412 (EP '412).

WO, discussed above, teach gelatin as a base for the preparation of spray-dried tablets. However, WO does not teach the claimed polysaccharides of the instant gums.

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EP '412 teaches finely divided pulverous carotenoids preparations formed by suspending the active ingredient in an organic solvent, feeding the suspension to a heat exchanger, rapidly mixing with a swellable colloid. EP teaches the particle size such as 213 nm, 225 nm or 400 nm. Among the colloids, EP teaches gelatin, starch, gums, pectin etc (col. 3, L 1-7).

It would have been obvious for one of an ordinary skill in the art at the time of the instant invention to prepare the tabletable powders of WO by incorporating colloids such as polysaccharide gums such as those taught by EP because EP suggests colloids such as gelatin and gums as equivalent in preparing vitamin powder preparations.

Accordingly, absent any unexpected advantage, it would have been within the scope of a skilled artisan to optimize the amounts of vitamins and colloids, based on the colloid employed, so as to prepare vitamin powder preparations with the claimed particle sizes.

Conclusion

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 12-22-06 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591.

The examiner can normally be reached on 7.00 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AU 1615
March 5, 2007



LAKSHMI S. CHANNAVAJJALA
PRIMARY EXAMINER